Claim 46, lines 1-2, delete "long-lasting".

Claim 47, line 2, delete "collar or".

REMARKS

Reconsideration of this application is respectfully requested.

Claims 1-17 and 21-47 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite in view of the words set out on page 2 of the Office Action. The above amendments address and overcome each of these objections.

Claims 1-47 have been rejected under 35 U.S.C. §112, first paragraph, as non-enabling. The above amendment introducing the test that defines the efficacy overcomes this objection. Support for the test regarding efficacy can be found on page 14, first two paragraphs, Example 2 and tables 6 and 7.

Support for the new claims can be found on page 5, second and third paragraphs; page 11, line 28 to page 12, line 16; and page 13, lines 4-10 of the specification.

Claims 1-47 have been rejected under 35 U.S.C. §102(b) as anticipated by Buntain et al (EPO 0,295,117) and under §102(e) as anticipated by Senbo. Claims 1-4 have also been rejected under 35 U.S.C. §103(a) as being unpatentable over Buntain et al, Huang et al, and Senbo. Each of these rejections are respectfully traversed.

In Buntain et al, the active compounds are described as being active against a very large number of parasites encountered in various fields, i.e., agriculture, public health, human medicine, and veterinary. Also, in the latter field, these substances may

act against a great number of parasites, for example, against fleas and ticks of companion animals such as cats and dogs. These substances may be applied in various ways, i.e., by the oral, parenteral, percutaneous, or topical ways. The latter type of administration itself includes various possibilities, i.e., sprays, dusts, baths, dips, shower, jets, greases, shampoos, creams, wax-smears, or pour-on preparations and devices attached externally to animals to provide local or systemic treatment. This is thus a very general prior art.

Example 12 of this prior document describes a slow release composition which could be used in the fabrication of collars or ear-tags for attachment to domestic animals to control insect pests by slow release of the pyrazole compound. It does not identify the animals to be treated nor the parasites.

However, the document does not constitute a technical teaching which makes it possible for one of ordinary skill in the art to consider using a device as claimed in the present application to ensure the high level of efficacy for the long period as presently claimed, i.e., to ensure more than six months of efficacy of greater than 95% against fleas and more than three months of efficacy of greater than 80% against ticks, the efficacy preferably being maintained for several weeks when the collar or external device is taken off or lost or if there is a variation in the release of the compound by the matrix.

First, the composition Example 12 does not indicate that the collar could be used specifically against fleas and ticks of dogs and cats and further does not indicate that this could be as efficient as herein disclosed.

Second, there is a problem linked to all collars presently marketed or used. One skilled in the art could not have envisaged that a collar could be a solution to the problem of protecting domestic animals against fleas and ticks as is claimed.

Despite the pesticidal activity which is claimed by the producers of conventional collars out in the field, the collars do not have the efficacy required to ensure the actual elimination of these parasites. The reason for this may be the low activity of the active substance included in the matrix. Another reason may be the accelerated degradation of these active substances under the effect of climatic factors, such as light, heat, and rain. ***Lastly and importantly, control of the release of the active substance from the matrix is largely over-evaluated.*** Release generally proves to be difficult and variable, and may depend greatly on the manufacturing conditions, which may vary from one batch to another, and on the conditions of use, in particular, climatic variations and especially humidity and temperature, etc. In addition, only a relatively small amount of the active substance incorporated is actually released and it proves difficult to be able to control and optimize its release.

Another drawback of the collars encountered in practice arises from the mode of use of this device which may, obviously, be taken off, worn irregularly, or even be pulled off when the animal moves about, for example, in undergrowth; the problem is particularly critical for hunting dogs whose collars are removed before a hunting outing even though they will be confronted with a flea- and tick-ridden environment.

As for the pesticidal compound of the prior art, a specialist might have expected to encounter conventional problems of release from the collar and thus problems of activity.

It was observed, very surprisingly, that the compounds according to the invention, which are very lipophilic and of high vapor pressure (low volatility), had a very high affinity for the sebum which usually covers the animal's coat (skin and hair), such that, when released, ***this compound is taken up by the sebum***, after what a translocation phenomenon occurs via the sebum ensuring distribution of active substance over the animal's entire body. In addition, and this is a noteworthy point, ***these active substances become concentrated in the sebaceous glands which become a reservoir for them,*** ensuring very long-lasting efficacy and making it possible to compensate for temporary absence of the collar or compound release variation (i.e., resulting from changes in climatic conditions), ***by releasing the active substance by passive diffusion***.

It is only from this finding that the applicant had been able to envisage, and that one skilled in the art could have seriously envisaged preparation and use of collars or similar devices to efficiently act against fleas and ticks and ensure more than six months of efficacy against fleas and more than three months of efficacy against ticks, the efficacy preferably being maintained for several weeks when the collar or external device is taken off or lost or if there is a variation in the release of the compound by the matrix.

Like Buntain, Senbo also presents a catalog of many kinds of formulations, targeted pests, and domestic animals to be treated but also fails to disclose that a particular collar as defined in amended claim 1 could be made.

Formulation Example 4 relates to a collar for pets. However, there is no description of an assay therewith.

Thus, this document fails also to disclose to the one skilled in the art that a particular collar which must have the efficacy as defined in amended claim 1 can be obtained with the active compound according to the invention.

Besides, to propose an efficient formulation, e.g., a collar, Senbo teaches that the aryldiazole must be associated with an insect growth regulator.

The arguments presented with respect to Buntain are also valid for Senbo.

As a result, it is evident that one skilled in the art would not have considered these prior documents as operational technical teachings which make it possible to obtain collars having the characteristics and properties claimed as indicated.

As a result, the invention as presently claimed (composition of matter and method), is not anticipated by these documents.

It is also evident from the above explanations that the claimed objects are unobvious with respect to these prior documents.

Nothing in these prior documents could have suggested to one skilled in the art that such efficacy could be obtained with all advantages, which are described in the specification such as: (1) a long-lasting efficacy not obtained with any prior collars or similar devices, (2) the possibility of taking off the collar without consequences on the

protection of the animal, and (3) the combined action of the collar and the sebum/the sebaceous glands to ensure all the above advantageous characteristics.

The finding by the present inventors that there is a relationship between the active compounds claimed and the sebum/sebaceous glands is unobvious and meritorious.

In summary, the level of efficacy obtained with the collars according to the invention is unexpected and surprising, and so is the relationship between the active compound and the sebum/sebaceous glands which surprisingly ensure efficacy even in the absence of the collar.

In view of the above amendments and for the reasons advanced, it is respectfully submitted that the claims are now in proper form and patentable over the references cited. Early reconsideration and allowance are earnestly solicited.

Respectfully submitted,

LARSON AND TAYLOR

Date: June 15, 1998

Thomas P. Sarro
Registration No. 19,396

Suite 900
1199 North Fairfax Street
Alexandria, Virginia, 22314
(703) 739-4900